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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
08/908,884	08/08/97	DONG	X	00786/33904

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EXAMINER	
NELSON, A	
ART UNIT	**PAPER NUMBER**
1649	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/908,884	Applicant(s) Xinnian Dong, et al.
	Examiner Amy Nelson	Group Art Unit 1649

☒ Responsive to communication(s) filed on *Jun 10, 1999* .

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1, 2, 4-13, 15-29, 36, and 40-42* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1, 2, 4-13, 15-29, 36, and 40-42* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Specification

1. This application is informal in the arrangement of the specification. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) Title of the Invention.
(b) Cross-References to Related Applications.
(c) Statement Regarding Federally Sponsored Research or Development.
(d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
(e) Background of the Invention.
    1. Field of the Invention.
    2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) Brief Summary of the Invention.
(g) Brief Description of the Several Views of the Drawing(s).
(h) Detailed Description of the Invention.
(i) Claim or Claims (commencing on a separate sheet).
(j) Abstract of the Disclosure (commencing on a separate sheet).
(k) Drawings.
(l) Sequence Listing (see 37 CFR 1.821-1.825).

The "Brief Description of Drawings" should occur before the "Detailed Description of the Invention." Applicant should delete "Detailed Description of the Invention" from its present location, and reinsert the subtitle on page 21, below line 20.

2. Rejections under 35 U.S.C. 102(b), 102(e), and 103(a) have been withdrawn in view of Applicant's amendments to the claims and Applicant's arguments.

Claim Rejections - 35 USC § 112

3. Claims 1, 2, 4-13, 15-29, 36, and 40-42 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record set forth in the last Official action mailed 12/7/98. Applicant's arguments filed 6/10/99 have been fully considered but they are not persuasive.

Applicant asserts that to provide an adequate written description Applicant need only identify what is intended to be the claimed invention. Applicant has identified a family of related nucleic acid molecules encoding polypeptides comprising an ankyrin repeat and conferring disease resistance on transgenic plants. Hence, Applicant asserts that Applicant has not just described the NPR1 gene, but has described the genus of disease resistance genes comprising the structural feature of an ankyrin repeat (response, p. 8-11). Examiner responds that to provide an adequate written description, Applicant must describe the composition and structure of the claimed subject matter. Applicant has only described the composition and structure of a single nucleic acid molecule. The ankyrin repeat motif is merely a small region of the disclosed nucleic acid molecule, and does not constitute a complete written description for other related nucleic acid molecules,

particularly since ankyrin repeats are structural characteristics of other nucleic acid molecules not functioning in plant disease resistance. Furthermore, it is not at all clear that a family of nucleic acid molecules which encode polypeptides comprising an ankyrin repeat and conferring disease resistance exist. In view of the limited description by Applicant of a single nucleic acid molecule, it is not clear that Applicant was in possession of the invention as broadly claimed.

4. Claims 1, 2, 4-13, 15-29, 36, and 40-42 remain rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for claims limited to an isolated DNA molecule that encodes the polypeptide of SEQ ID NO:14, a vector, transformed host cell, and transgenic plant comprising said DNA molecule, and methods of producing said polypeptide in a host cell, and of providing increased disease resistance in a transgenic plant with said DNA molecule. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is repeated for the reasons of record set forth in the last Official action mailed 12/7/98. Applicant's arguments filed 6/10/99 have been fully considered but they are not persuasive.

Applicant asserts that Applicant need not reiterate techniques known to one of skill in the art, and that one of skill in the art could isolate additional nucleic acids falling within the scope of the claims using standard methods of gene cloning, such as hybridization or PCR amplification, followed by disease resistance analysis in transgenic plants. In particular, Applicant points to

pages 50-53 of the specification for guidance with respect to oligonucleotide primers which could be used in the isolation of related nucleic acids. Hence, Applicant argues that only routine experimentation would be required to practice the claimed invention, both for isolation of structurally related genes and for identification of those that confer disease resistance in transgenic plants (response, p. 11-17). Examiner responds that whereas methods of gene cloning via hybridization or amplification were well known in the art at the time of Applicant's invention, significant guidance is required to practice the techniques. Although Applicant teaches the composition and structure of a single gene sequence and suggests specific oligonucleotide primers which could be used in gene isolation, Applicant provides no specific guidance with respect to what probe or primer sequences in combination with what hybridization/wash conditions or PCR reaction conditions would result in successful isolation of structurally and functionally related genes. In the absence of such guidance, undue trial and error experimentation would be required to screen through the vast number of cDNA or genomic clones from *Arabidopsis*, from other plant species, or from other organisms, and to screeen through the myriad of transgenic plants transformed with said clones to identify other structurally and functionally related nucleic acids.

Applicant cites the disclosed *Nicotiana glutinosa* NPR1 homolog as evidence of other related nucleic acids. Furthermore, Applicant asserts that Examiner provides no scientific basis to doubt that structurally related genes would function similarly in disease resistance (response, p. 14-19). Examiner responds that, as discussed in the previous Official action, Applicant has provided no evidence to support the contention that the NPR1 "homolog" isolated from

Nicotiana glutinosa is functionally related to the disclosed NPR1 gene from *Arabidopsis*, and confers disease resistance on transgenic plants. The basis for doubting that structurally related nucleic acids would necessarily confer disease resistance in plants is that the ankyrin repeat motif has been identified in many different functionally unrelated proteins. Hence, structural relatedness alone is not sufficient basis to predict functional relatedness. Furthermore, the novelty of the instant invention is Applicant's identification of a structurally unique nucleic acid molecule which confers disease resistance on transgenic plants. In the absence of specific evidence from Applicant, one would not readily expect that other structurally and functionally related nucleic acid molecules occur in other plant species, or other biologically distinct organisms. Therefore, the scope of the claimed invention is not commensurate with the teachings of the specification, and the invention is not enabled.

With respect to Claim 36, Applicant asserts that in view of the "culturing" step, the claim clearly is limited to cells *in vitro* (response, p. 19). In response, Examiner has withdrawn this aspect of the rejection.

5. Claims 1, 2, 4-13, 15-29, 36, and 40-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At Claims 1, 10-12, and 36, the phrase "acquired resistance polypeptide" is indefinite. Applicant asserts that SAR and LAR are processes well known in the art, and hence the phrase is

not indefinite (response, p. 20-21). Examiner responds that although the processes are well known in the art, the processes are exceedingly complex and have not been well-elucidated. Applicant has not clearly defined functionally the role of an "acquired resistance polypeptide" in SAR or LAR responses. Also, many of the steps of SAR and LAR responses are also present in other physiological responses in plants. Hence, Applicant need clearly define the precise functional role of an "acquired resistance polypeptide." If Applicant intends a polypeptide which confers plant pathogen resistance, then all of the claims should be amended like Claim 1, to indicate that an "acquired resistance polypeptide" functions to confer resistance to a plant pathogen.

At Claim 4, line 2, the term "derived from" is indefinite. There are many different types of derivatives and Applicant has not clearly defined the phrase. Hence, it is not known what is encompassed by the claim. Appropriate correction is required to clarify the metes and bounds of the claimed invention. It is recommended that the phrase be changed to --from--.

At Claims 10-12, the phrase "specifically hybridizes to" is indefinite. Applicant asserts that low and high stringency conditions are well recognized in the art, and that one of skill in the art could easily identify a nucleic acid molecule encoding an acquired resistance polypeptide comprising an ankyrin repeat which specifically hybridizes to the disclosed NPR1 nucleic acid molecule, whether under low or high stringency conditions (response, p. 21-23). Examiner responds that "specifically" is a relative term dependent on hybridization conditons. If Applicant intends a nucleic acid molecule which hybridizes to the NPR1 nucleic acid molecule and not to any other nucleic acid molecule, then such a limitation is dependent on the conditions under which

the hybridization occurs, conditions which have not been defined in the claim or in the specification. Moreover, Applicant attempts to define the phrase at page 12 of the specification, but fails to clarify whether low or high stringency conditions are intended and what those low or high stringency conditions are. Low and high stringency conditions have many different definitions in the art, and absent of specific hybridization/wash condtions, are indefinite. Examiner recommends that Applicant amend the claims to recite specific hybridization/wash conditions disclosed in the specification.

At Claim 13, the term "mediates" is indefinite. Applicant asserts that this rejection has been overcome by amendment of Claim 2 (response, p. 23). Examiner responds that Claim 13 is not dependent on Claim 2, and hence amendment of Claim 2 does not overcome this rejection. Applicant is advised to amend Claim 13 similar to Claim 2, in order to obviate the rejection.

At Claims 36 and 40, the phrase "positioned for expression in the plant cell" is indefinite. Applicant asserts that the phrase is defined at page 12 of the specification (response, p. 24-25). Examiner responds that the definition at page 12 of the specification is indefinite in that it recites that "the DNA molecule is positioned adjacent to a DNA sequence which directs transcription and translation of the sequence." It is unclear how the DNA molecule can be adjacent to a DNA sequence (*e.g.* promoter), wherein the DNA sequence (*e.g.* promoter) can direct transcription and translation of the DNA sequence (*e.g.* promoter). It is recommended that Applicant amend the specification to change the second occurrence of "sequence" to --DNA molecule--. Also, in that claims 36 and 40 recite a vector positioned for expression in the plant cell, it is unclear how a

vector (a circular piece of DNA) is adjacent to a DNA sequence. Appropriate correction to the claims is required to clarify this aspect of the rejection.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy J. Nelson whose telephone number is (703) 306-3218. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909. The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application, or if the examiner cannot be reached as indicated above, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Amy J. Nelson, Ph.D.
July 20, 1999

L. F. Smith

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